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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,454	12/13/2006	Timothy Vollmer	68682-PCT-US/JPW/JW	1309

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
04/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/556,454	VOLLMER, TIMOTHY	
	Examiner	Art Unit	
	MAURY AUDET	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The present application is a 371 National Stage entry of PCT/US04/15225, in which this Examiner also prepared both the Search & Written Reports (Forms 210 and 237 respectively) on the identical claims 1-25. The latter found that the invention, although finding Novelty under PCT Article 33(2), was not deemed to involve an Inventive Step under PCT Article 33(3). The findings therein, are transferred nearby verbatim via the US correlational Statutory Code section 35 USC 103.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The invention is drawn to the composition and method of treating a subject afflicted with multiple sclerosis with the combination of active agents glatiramer acetate and mitoxantrone.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szabo et al (US 6,531,464) in view of Arnon et al. (US 6,214,791) and Kerwar et al. (US 4,617,319).

Szabo et al. teach "administering one or more additional agents for treating symptoms associated with multiple sclerosis") of glatiramer acetate and mitoxantrone (claim 11, as two of only five specifically contemplated "additional agents" also capable of treating multiple sclerosis) (see entire document, especially claims 10-11).

Arnon et al. teach the use of glatiramer acetate as the primary agent for the treatment of multiple sclerosis, in a therapeutically effective amount through any means of administration (see entire document, especially claims 1 and 8; col. 1, lines 35-41; and Fig. 8).

Kerwar et al. teach the use of mitoxantrone (TradeName NOVANTRONE) as the primary agent for the treatment of multiple sclerosis, in a therapeutically effective amount through any means of administration (see entire document especially claim; col. 1; lines 5-9).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a combination composition comprising the active agents glatiramer acetate and mitoxantrone for the treatment of a subject afflicted with multiple sclerosis, in Szabo et al. because SZABO et al. teach adminstration of the combination (claim 10, i.e. "administering one or more additional agents for treating symptoms associated with multiple sclerosis") of glatiramer acetate and mitoxantrone (claim 11, as two of only five specifically

contemplated "additional agents" also capable of treating multiple sclerosis). ARNON et al. teach the use of glatiramer acetate as the primary agent for the treatment of multiple sclerosis, in a therapeutically effective amount through any means of administration (claims 1 and 8, col. 1, lines 35-41, and Fig. 8). KERWAR et al. teach the use of mitoxantrone (TradeName NOVANTRONE) as the primary agent for the treatment of multiple sclerosis, in a therapeutically effective amount through any means of administration (claims, col. 1, lines 5-9). Based on the combination of references, it would have been predictable to one of ordinary skill in the art, at the time of the invention, to effectively administer the exclusive combination of glatiramer acetate and mitoxantrone, as primary agents (rather than only additional/secondary agents) for the treatment of multiple sclerosis in SZABO et al., because ARNON et al. teach the advantageous use of glatiramer acetate as the primary agent for the treatment of multiple sclerosis and KERWAR et al. teach the advantageous use of mitoxantrone (TradeName NOVANTRONE) as the primary agent for the treatment of multiple sclerosis.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA, 3/28/09

/Maury Audet/
Examiner, Art Unit 1654